

Remarks

Applicants thank the Examiner for noting the allowability of claim 2. Further, Applicants have amended the claims so that only two specific erythropoietin purification protocols are claimed. In the first claim set (claims 1 and 4-12), the order of the purification steps is the same as in allowable claim 2. The second claim set (claims 17-26) is directed to a protocol as recited in original claim 3 and described in the Declaration of Dr. Marcelo E. Criscuolo under 37 C.F.R. § 1.132, as filed with the December 1, 2004 Amendment and Reply. The foregoing amendments are believed to place the application either in condition for allowance or in better form for appeal and do not raise new issues for consideration by the Examiner.

Upon entry of the foregoing amendment, claims 1, 4-12 and 17-26 are pending in the application, with 1 and 17 being the independent claims. Claims 2, 3 and 13-16 are sought to be cancelled without prejudice to or disclaimer of the subject matter therein. New claims 17-26 are sought to be added. Support for these amendments is found throughout the specification, in particular at page 7, line 26 through page 8, line 9, as well as in the originally filed claims. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Rejections under 35 U.S.C. § 112

The Examiner maintained the rejection of claims 1 and 3-12 under 35 U.S.C. § 112, first paragraph, because

[t]he specification, while being enabling for a method of purifying recombinant human erythropoietin (EPO) from cell culture supernatants via employing the order of process steps recited in claim 2, does not reasonably provide enablement for purifying human recombinant EPO from any and all cell culture supernatants via any order of the combination of numerous recited process steps instantly claim. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

(See the Office Action at 2.)

Applicants respectfully disagree with the Examiner's rejection. Applicants maintain that the specification as filed enables a person skilled in the art to make and use the invention commensurate in scope with the claimed invention. However, solely in the interest of expediting prosecution, and not in acquiescence to the Examiner's rejection, Applicants have amended the claims without prejudice or disclaimer to the subject matter contained therein. The claims are now directed to two specific erythropoietin purification protocols.

In the first claim set (claims 1 and 4-12), the order of the purification steps is the same as in allowable claim 2: (a) differential saline precipitation; (b) hydrophobic interaction chromatography; (c) concentration and diafiltration; (d) anionic exchange chromatography; (e) cationic exchange chromatography; (f) concentration and diafiltration; and (g) molecular exclusion chromatography.

The second claim set (claims 17-26) is directed to a protocol as recited in claim 3 as filed and as described in the Declaration of Dr. Marcelo E. Criscuolo, filed on December 1, 2004, and contains the following steps, in order: (a) differential saline precipitation; (b) concentration and diafiltration; (c) anionic exchange chromatography; (d) cationic exchange chromatography; (e) hydrophobic interaction chromatography; (f) concentration and diafiltration; and (g) molecular exclusion chromatography.

Both of the claimed protocols have been performed as described in the specification, with the resulting erythropoietin yield and purity being similar between the two protocols. In view of the guidance provided by the specification and the knowledge of those skilled in the art, it is clear that one of skill in the protein purification art would not have to perform any undue experimentation in order to arrive at the instant invention. Therefore, Applicants believe that this rejection is moot and should be withdrawn.

Rejections under 35 U.S.C. § 102

The Examiner again rejected claims 13-16 under 35 U.S.C. § 102(b) as allegedly being anticipated by Rosen (WO 92/06116).

Solely in the interest of advancing prosecution, and without prejudice to or disclaimer of the subject matter contained therein, Applicants have canceled claims 13-16. Therefore, Applicants believe that this rejection is now moot, and should be withdrawn.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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